Complaint Handling: Not Quite Nirvana, But Required

Alan G. Minsk

We recently spoke at a program on product complaints for life science companies, and officials from the Food and Drug Administration's Pacific Region spoke. While our particular topic focused on applying certain FDA guidance on social media to adverse event reporting and complaint handling obtained through social media, FDA's session was a more basic overview on product complaints. The rock band Nirvana's song lyric from "Heart Shaped Box" -- "I've got a new complaint – forever in debt to your priceless advice" – came to mind. This Bulletin should explain why.

We will not describe here FDA's adverse event report or complaint requirements. However, we thought some of the officials' observations, expectations and recommendations are noteworthy. While many may appear to be obvious, it is always useful to try to understand the agency's current thinking when preparing for an inspection.

Complaint Investigation

- The investigation should be timely and thorough
- The investigation should be easy to follow (i.e., in a narrative format with supporting documentation)
- Attempt to obtain missing information from the complaint or adverse event reporter
- Request and analyze the complaint sample
- Include photographs of the defect, if possible
- Identify foreign objects in the product
- Perform a batch record review
- Inspect and analyze reserve samples
- Search databases for previous similar complaints or trends; extend the investigation to other lots that may be affected with the same problem
- Explore potential causes of the problem and investigate
- Identify a root cause with adequate supporting evidence
- Evaluate the complaint for regulatory reporting obligations
- Make a conclusion about product impact with adequate justification
- Recommend a corrective and preventative action
- Investigation should be reviewed and approved by the company's Quality Assurance department

Red Flags Noted by FDA

- Dismissal of the complaint because no sample could be obtained
- Not counting the complaint in trending due to status of "unconfirmed," (i.e., claiming the company cannot confirm the product caused the problem)
- Concluding the problem is due to user error or improper handling

Complaint Handling Deficiencies

The conference focused on complaint handling so, naturally, the FDA official discussed trends in complaint handling deficiencies, as evidenced by observations in FD-483s. The investigator, citing current Good Manufacturing Practices for drug products (21 C.F.R. § 211.198 and complaint files),

noted that, since January 1, 2013, FDA issued 188 citations for violations of the complaint handling requirement. (While the discussion centered on drug GMPs, similar concerns apply to device companies.) In particular, common deficiencies specifically included:

- Lack of, or inadequate, complaint handling procedures
- Failure to follow complaint handling procedures
- Complaint handling procedures lack provisions for determination of adverse event reporting
- Complaint file not maintained in the correct location
- Complaint record lacks the required information
- Complaint record lacks findings of the investigation

Investigations

According to the FDA speaker, the agency issued 421 citations in the last two years for failing to comply with the investigations regulation (described at 21 C.F.R. § 211.192). Specifically, the investigator identified several types of FD-483 trends relating to poor investigations:

- Failure to thoroughly review discrepancies
- Failure to include conclusions and follow up in investigations
- Failure to extend investigations to other batches
- No requirement for the pharmacovigilance group (or other departments) to share information with the quality unit
- No diligence in follow up to obtain missing information from complainant.
- No Field Alert report filed when indicated
- Lack of timely investigation; numerous investigations still open
- Failure to identify or characterize foreign matter
- Issues with contract arrangements; lack of timely notification of complaints

AGG Observations

- Some of us remember the classic exchange from the Seinfeld television episode:

  You see, you know how to “take” the reservation, you just don’t know how to “hold” the reservation. And that’s really the most important part of the reservation – the holding.

Similarly, anyone can take a complaint. But one must also investigate the complaint. And, here is where many companies fall short.

- Look at big picture, i.e., trending
- Be thorough, organized and timely in complaint handling and investigation
- Minimize excuses and conjecture; work diligently and evaluate critically to focus on the problem
- Play nicely in the sandbox with the company’s internal team and external team, such as third-party vendors, to gather information to investigate
- Look at present situation, but look to the past (for similar problems) and future (to minimize a recurrence)

To paraphrase Nirvana, if you have a new complaint, seek advice, internally and externally, and investigate. It can be priceless.

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